



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,980	12/27/2000	Elaine Lee	8600-0010	6822

23419 7590 10/08/2003

COOLEY GODWARD, LLP
3000 EL CAMINO REAL
5 PALO ALTO SQUARE
PALO ALTO, CA 94306

EXAMINER

BAXTER, JESSICA R

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/08/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/749,980

Applicant(s)

LEE, ELAINE

Examiner

Jessica R Baxter

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,14-17,19,21-32 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,14-17,19,21-24,31,32 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 4, 11, 14, 17, 19, 21 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,231,590 to Slaikeu et al.

Slaikeu discloses a vaso-occlusive composition consisting of a coil and a bioactive material that comprises at least one cytokine selected from the group consisting of PDGF, bFGF, VEGF and TGF-beta (Column 7 line 22-Column 8 line 58).

Slaikeu discloses a tie layer between the vaso-occlusive member and the bioactive material (Column 3 lines 23-37).

Slaikeu discloses that the vaso-occlusive member is plasma treated (Column 3 lines 30-32).

3. Claims 1, 5, 6, 19 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,458,127 to Truckai et al.

Truckai discloses a vaso-occlusive composition consisting of a coil and a bioactive material comprising a trace metal comprising copper (Column 6 lines 47-54 and Column 7 lines 25-33).

Art Unit: 3731

4. Claims 1, 7 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,669,931 to Kupiecki et al.

Kupiecki discloses a vaso-occlusive composition consisting of a coil and a thrombus stabilizing molecule (Column 6 lines 11-17).

5. Claims 37 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,638,803 to Rand.

Rand discloses a vaso-occlusive composition comprising a vaso-occlusive member of a balloon coated with iron microspheres (Column 2 line 63-Column 3 line 8).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8, 9, 10 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki et al. '931.

Kupiecki discloses the claimed device except for the use of Factor XIII, plasminogen activator inhibitor-1 (PAI-1) or α_2 -antiplasmin as the thrombus-stabilizing molecule. It is well known that Factor XIII, PAI-1 and α_2 -antiplasmin may all be utilized to prevent a thrombus from breaking up. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the thrombus stabilizing factor provided by Kupiecki with Factor XIII, PAI-1 or α_2 -antiplasmin, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its

Art Unit: 3731

suitability for the intended use as a matter of obvious design choice and there is no stated reason for using one thrombus-stabilizing molecule over another.

8. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki et al. '931 in view of U.S. Patent No. 5,891,192 to Murayama et al.

Kupiecki discloses the claimed invention except for the vaso-occlusive member being subjected to ion implantation. Murayama teaches that ion implantation alters the surface properties of a metal implant such as thrombogenicity, endothelial cellular migration and adhesion, minimally increases the dimensions of the implant, and increases the fixation of a protein coating on the metal surface of the implant (see Column 3 lines 21-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the metal implant of Kupiecki to include the application of ion implantation in order to change the surface properties including thrombogenicity, endothelial cellular migration and adhesion, minimally increase the dimensions of the stent, and to increase the fixation of the protein on the surface of the metal coil.

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki et al '931 in view of U.S. Patent No. 6,256,979 to Nikolchev et al.

Kupiecki discloses the claimed invention except for the vaso-occlusive member being microtextured. Nikolchev discloses that an occlusive member is microtextured in order to promote tissue ingrowth and enhance the occlusion of the vessel (Column 14 lines 9-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Kupiecki with the microtexturing of Nikolchev in order to enhance tissue ingrowth and occlude the vessel.

10. Claims 31, 32, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,690,666 to Berenstein et al. in view of WO 00/27445 to Boock et al.

Berenstein discloses a vaso-occlusive composition comprising a coil and a particulate liquid embolic material (Column 5 line 66-Column 6 line 9). Berenstein does not disclose an additional bioactive material selected from the group consisting of at least one cytokine, extracellular matrix material, DNA, RNA, functional fragments of DNA and RNA and combinations thereof. Boock teaches that a bioactive material is attached to a vaso-occlusive coil in order to reduce friction, provide a therapeutic for local or blood borne delivery, or enhance thrombosis, coagulation or platelet activity (Page 11 line 17-page 14 line 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the composition of Berenstein with the bioactive material of Berenstein in order to reduce friction, provide a therapeutic for local or blood borne delivery, or enhance thrombosis, coagulation or platelet activity.

11. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berenstein et al. '666 in view of WO 00/27445 to Boock et al. as applied to claims 31, 32, 35 and 36 above, and further in view of Murayama et al. '192.

Berenstein, as modified, discloses the claimed invention except for the coil being absorbable. Murayama teaches that a coil may be made out of known absorbable or non-absorbable materials for implants (Column 2 lines 37-50). It would have been obvious to make the coil of Berenstein out of an absorbable material, as taught by Murayama, since it is well-known in the art to make implants out of either absorbable or non-absorbable materials.

Response to Arguments

12. Applicant's arguments filed July 21, 2003 with respect to claims 31, 32 and 34-36 have been fully considered but they are not persuasive.

Art Unit: 3731

13. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Berenstein teaches that a coil may be filled with a bioactive material (Column 4 lines 42-46) and an additional material is injected into the surgical site (Column 5 line 66-Column 6 line 9). Boock teaches a variety of bioactive materials that may be utilized with a vaso-occlusive coil (page 11 line 17 -page 14 line 17).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3731

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

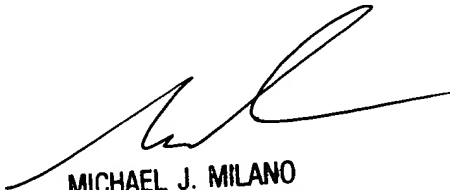
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9302 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731


rb

October 6, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700